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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,316	01/22/2002	Hugo Streekstra		4091
7590		07/12/2004		
Lerner & Greenberg PO Box 2480 Hollywood, FL 33020-2480			EXAMINER HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 07/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/936,316		STREEKSTRA ET AL.	
	Examiner		Art Unit	
	San-ming Hui		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/31/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendments filed 1/22/2002 have been entered.

Claims 1-12 are pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 provides for the use of a sphingoid base, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The expression "01005 to 5 wt %" recited in claim 10 renders the claim indefinite as to the weight percent of the active compound encompassed therein. It is apparent that the "01005 to 5 wt %" is a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma catalogue 1997, pages 863 and 973.

Sigma teaches phytosphingoidsine hydrochloride and sphingoisine sulfate (See Product no. P2795 and S3263).

Claims 1-4, 6, 8, 9, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 373 038 (the reference is from the IDS filed January 31, 2002).

'038 teaches sphingoisine derivative which can be prepared as succinate and sulfate (See page 9, line 48 and page 13, Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over '038.

'038 teaches the method of preparing sphingosine salt by adding sulfuric acid to isopropanol solution containing sphingosine base so that the salt of sphingosine would be precipitated in isopropanol(See page 13, Example 3).

'038 does not expressly teach the recrystallization using ethanol or methyl isobutyl ketone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute isopropanol with ethanol as the solvent.

One of ordinary skill in the art would have been motivated to substitute isopropanol with ethanol as the solvent. Ethanol and isopropanol are both well-known organic solvents. Substitution of isopropanol with ethanol would therefore be seen as substitution with the obvious alternatives.

Claims 1, 8, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/49999 (the reference s from IDS filed January 31, 2002) in view of Gould (International Journal of Pharmaceutics, 1986;33:201-217).

'999 teaches sphingosine, in an amount of 0.02 to 0.5 wt%, as effective in a method of treating fungal infection (See claims 3 and 5).

'999 does not expressly teach the employment of sphingosine salt in the method of treating fungal infection.

Gould teaches the selection of salt for basic drugs as routine in order to optimize the desirable physical and chemical properties of the drugs (See the abstract and page 211, col. 2, last paragraph bridging to page 213 last paragraph). Gould also teaches that salt formation provides a means of altering the physiochemical and resultant biological characteristics of a drug without modifying its chemical structure (See page 201, col. 1, first paragraph). Gould also teaches that by selecting the suitable salt for the active, one of ordinary skill in the art can alter the solubility, absorption, stability, and toxicity of the drug (See page 204 – 213, especially, page 212, and 213 on melting

point, solubility and stability). Gould also teaches that each drug and its associated range of dosage forms will present different salt form requirements (See page 204, col. 1, last paragraph): for example, in page 211, Fig. 5, Gould teaches that increase solubility is desired for increasing bioavailability.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the salt of sphingosine in the antifungal method of '999.

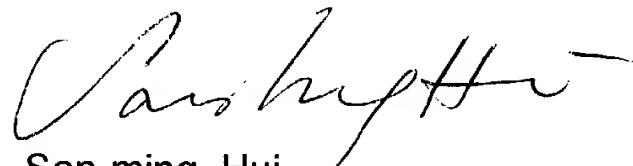
One of ordinary skill in the art would have been motivated to employ the salt of sphingosine in the antifungal method of '999. In view of Gould selecting salt of sphingosine to optimize the desirable properties of the drugs as obvious and routine practice in the pharmaceutical art. Therefore, employing the salt of sphingosine in the antifungal method of '999 would have been obvious, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Patent Examiner
Art Unit 1617